Filed 8/10/04 American Environ. Safety Inst. v. Denton CA2/5

NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FIVE

AMERICAN ENVIRONMENTAL SAFETY INSTITUTE et al., Appellants, v. JOAN E. DENTON et al., Respondents.	B168154 (Los Angeles County Super. Ct. No. BC279638)

APPEAL from a judgment of the Superior Court of Los Angeles County. David P. Yaffe, Judge. Affirmed.

The Carrick Law Group and Roger Lane Carrick for Appellants.

Bill Lockyer, Attorney General of the State of California, Tom Greene, Chief Assistant Attorney General, Theodora P. Berger, Senior Assistant Attorney General, and Edward G. Weil, Supervising Deputy Attorney General, for Respondents.

This case arises under the Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65. (Health & Saf. Code, §§ 25249.5 et seq.) Appellants American Environmental Safety Institute and the Center for Ethics and Toxics filed a petition for writ of mandate and complaint for declaratory relief challenging a regulation which established a level of cadmium exposure safe enough to be exempt from the Proposition 65 warning requirement. (Health & Saf. Code, § 25249.10, subd. (c).) Appellants sought an order directing the Office of Environmental Health Hazard Assessment ("OEHHA") and its director Joan Denton, both respondents here, to withdraw the regulation and an order declaring the regulation unlawful. The trial court denied the petition and dismissed the complaint for declaratory relief. We affirm.

The regulation and the regulatory scheme

Under the Safe Drinking Water and Toxic Enforcement Act of 1986, no business may knowingly expose anyone to a chemical known to cause reproductive toxicity without first giving that person a clear warning. (Health & Saf. Code, §§ 25249.5, 25249.6.) However, no warning need be given for an exposure to a reproductive toxin if "the person responsible can show . . . that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question . . . , based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical . . . ." (Health & Saf. Code, § 25249.10, subd. (c).) The Act also directs the Governor to cause to be published a list of chemicals known to the state to be reproductive toxins. (Health & Saf. Code, § 25249.8.)

Under the Act, "A chemical is known to the state to cause . . . reproductive toxicity . . . if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause . . . reproductive toxicity . . . ." (Health & Saf. Code, § 25249.8, subd. (b).) The members of the OEHHA's Development and Reproductive Toxicant Identification ("DART") Committee, who must have expertise in such areas as developmental toxicology,

reproductive toxicology, teratology, medicine, public health, biostatistics, and biology, are the state's qualified experts on reproductive toxins. (Cal. Code Regs., tit. 22, § 12102, subd. (c)(2); § 12302, subd. (a)(2).)

The DART Committee evaluated cadmium in 1996. It was listed as a reproductive toxin in 1997. Notably, the DART Committee report on cadmium cites hundreds of references, one of which was a study conducted by a Dr. Baranski, and another of which was conducted by a Dr. Ali.[1]

The statutory scheme also provides that a lead agency may issue regulations implementing the statute. (Health & Saf. Code, § 25249.12.) The OEHHA is the relevant lead agency. In June of 2001, that agency issued a notice of proposed Maximum Allowable Dose Levels ("MADLs") for five reproductive toxins, including cadmium.

OEHHA's Final Statement of Reasons for the regulation explains the reason for the regulation: by establishing the level of exposure exempt from the warning requirement, the regulation provides a safe harbor for businesses which are covered by the Act but which do not have the resources to make scientific determinations about toxicity.[2]

The OEHHA proposed a MADL for cadmium of 4.1 micrograms a day, based on the Ali study.

OEHHA sought comments from the public with its proposal and again in March of 2002, after it had studied the initial comments. Appellants were among the commenters.

---

[1] Appellants argue that the Baranski study was a "key" study. OEHHA disagrees. We see nothing in the DART Committee's report or the transcript of its public meeting on the issue or any of the other materials referenced by appellants which would suggest that the Baranski study was a key study.

[2] Appellants seem to argue that OEHHA improperly created the regulation "to assist business," something which, in appellants' view, renders the regulation "illegal," given that the intent of Proposition 65 was to protect the public. We can see no impropriety or illegality. The regulation will indeed assist businesses, by making it easier for them to comply with the law, surely better for the public than violation of the law would be.

They suggested that the Baranski study was the appropriate basis for setting the cadmium MADL. (According to appellants, if the Baranski study was used, the MADL would be 0.232 micrograms a day.)

OEHHA reviewed appellant's comments, spoke to appellant's representatives, and considered the additional information they provided, and determined that the Baranski study was "unsuitable for quantitative risk assessment."

OEHHA's Final Statement of Reasons for the MADL explains that "For example, the [Baranski] paper did not specify the numbers of pregnant females [rats] exposed to cadmium. It appears that only eight offspring of each sex for each treatment group were assessed postnatally, although the presentation of the data is ambiguous and may only represent a total of eight offspring per treatment group. No indication of the number of litters represented was provided, nor was any information provided on whether the pups were randomly selected in a balanced fashion across litters or from a pool of pups from all litters reported in each dose group . . . ."

In June, OEHHA finalized the regulation at 4.1 micrograms a day. The regulation was approved by the Office of Administrative Law in July.

Discussion[3]

Appellants argue that the OEHHA acted outside the law by basing the cadmium MADL on anything other than the Baranski study, that there is no substantial evidence for the regulation because it did not rely on the Baranski study, and that by determining that it was not bound to use the Baranski study, OEHHA interpreted Health and Safety Code section 25249.10, subdivision (c) and California Code of Regulations, title 22, section 12803 (and got it wrong), thus triggering a de novo review. For the same

[3] Appellants' request that we take judicial notice of various documents relevant to the Proposition 65 drafters' intent is denied. The documents are not relevant to our discussion here.

reason, they argue that the cadmium regulation transgressed OEHHA's statutory authority and is thus void.[4]

Appellants do not challenge California Code of Regulations, title 22, section 12803, subdivision (a)(4), but argue that under that regulation and Health and Safety Code section 25249.10, subdivision (c), OEHHA must base a MADL on the most sensitive of the studies relied on to list the chemical. They argue that the Baranski study is the most sensitive study,[5] and thus that the current regulation is invalid under all the legal theories listed above.

The first part of the argument is based on that portion of Health and Safety Code section 25249.10, subdivision (c) which mandates that the exposure level which is exempt from the warning requirement be determined "based on evidence and standards of comparable scientific validity to the evidence and standards . . . for the listing of such chemical . . . . " (Health & Saf. Code, § 25249.10, subd. (c).) Appellants read this to mean that levels must be established by using *the same* information used in the determination that the chemical is a reproductive toxin. (In contrast, OEHHA argues that "comparable" means "comparable.")

Appellants then cite that portion of California Code of Regulations, title 22, section 12803, which recites the statutory mandate that quantitative risk assessment be based on evidence of comparable scientific validity to the evidence which formed the basis for listing the chemical, then provides that "In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following

---

[4] Appellants also make an argument based on the trial court ruling that the OEHHA was not a "person" under the Health and Safety Code section 25249.10, subd. (c), and need not comply with that statute. Appellants urge us to find that the trial court was wrong. We do not reach the issue, because we do not believe that it is properly before us. OEHHA's position is that it was bound by the statute, and it defended the regulation on that basis.

[5] OEHHA does not agree that the Baranski study was the most sensitive study, given its lack of statistical reliability.

default principles and assumptions shall apply in any such assessment: . . . 4) The NOEL [no observable effects level] shall be based on the most sensitive study deemed to be of sufficient quality."[6] Appellants argue that this means that the MADL must be based on the most sensitive of the studies used in the determination that the chemical is a reproductive toxin. (OEHHA, in contrast, argues that it may, indeed must, decide whether the most sensitive study used earlier is of sufficient quality for use in determining a safe level.)

We agree with OEHHA. Health and Safety Code section 25249.10, subdivision (c) provides that the evidence must be of comparable validity to the evidence relied on to list the chemical, not that it be the same evidence. By using the word "comparable," the statute clearly contemplates that the evidence may *not* be the same. Appellants' interpretation of the statute is not supported by the words thereof. Moreover, were we to adopt appellants' interpretation, OEHHA would not be permitted to use new evidence, no matter how valid, in setting MADLs, hardly a result which would further the public interest.

Nor do we see anything in the cited regulation which means that OEHHA's implicit finding that the Baranski study was of sufficiently quality to be of use in determining whether cadmium is a reproductive toxin necessarily means that the study is of sufficient quality for use in a different task, determining safe levels of exposure. As OEHHA points out, California Code of Regulations, title 22, section 12803, also provides that in determining safe levels, "(a)(3) Animal bioassay studies for assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, . . . the number and size of exposed groups . . . ."

Thus, if OEHHA interpreted the statute and regulation, it did so in exactly the way we do, and thus reasonably interpreted its legislative mandate. (*Nicolle-Wagner v.*

---

[6] A NOEL is (of course) the basis for a MADL.

Deukmejian (1991) 230 Cal.App.3d 652, 658.) Even under the strictest standard of review, we would not find that it acted outside its authority.

The remaining issues are subject to a deferential standard of review, where "'the trial court does not inquire whether, if it had power to act in the first instance, it would have taken the action taken by the administrative agency. The authority of the court is limited to determining whether the decision of the agency was arbitrary, capricious, entirely lacking in evidentiary support, or unlawfully or procedurally unfair.' [Citations.]" (*Fullerton Joint Union High School Dist. v. State Bd. of Education* (1982) 32 Cal.3d 779, 786.)

We do the same. (*Sherwin-Williams Co. v. South Coast Air Quality Management Dist.* (2001) 86 Cal.App.4th 1258, 1267.) "The courts exercise limited review of legislative acts by administrative bodies out of deference to the separation of powers between the Legislature and the judiciary, to the legislative delegation of administrative authority to the agency, and to the presumed expertise of the agency within its scope of authority." (*California Hotel & Motel Assn. v. Industrial Welfare Com.* (1979) 25 Cal.3d 200, 211-212.)

This case, which concerns the quality of rat studies, illustrates the wisdom of the deferential standard of review. We are not ashamed to say that we have no expertise in rats or the selection of rat offspring, and would not know a good choice of rats from a bad one. What the standard of review means is that our ignorance is of no moment. As long as OEHHA's decision was not arbitrary or capricious, and had evidentiary support, we defer to its expertise.

The OEHHA concluded that while the Baranski study was sufficiently valid to be one of the many studies relied on for the conclusion that cadmium is a reproductive toxin at some level, it was not of sufficient quality to be used to calculate the level of exposure exempt from the Proposition 65 warning requirement. Appellants attempt to persuade us that there was no problem with rat selection in the Baranski study, and indeed attempt to persuade us that the Ali study was flawed. That is not our decision to make. We say

only that given the problems with the Baranski study explicated by the OEHHA in the administrative record, we see nothing irrational or arbitrary in its decision.

Appellants make several other arguments. First, they contend that the Federal Agency for Toxic Substances and Disease Registry ("ATSDR") determined that the Baranski study was the most sensitive, and argue that under *Western Crop Protection Assn. v. Davis* (2000) 80 Cal.App.4th 741, the OEHHA was bound to rely on the study endorsed by the ATSDR. (The ATSDR is an agency within the Public Health Service, which, inter alia, is directed to prepare toxological profiles of various chemicals, based in part on review of scientific literature. (42 U.S.C. 9604, subd. (l).) *Western Crop Protection Assn., supra,* does not support the argument. Instead, that case discusses OEHHA reliance on the Federal Environmental Protection Agency as an "authoritative agency" under Health and Safety Code section 25249.8, which provides that a chemical shall be listed as a reproductive toxin if "a body considered to be authoritative" by the state's experts has identified it as such. (Health & Saf. Code, § 25249.8, subd. (b).)

Appellants make much of the fact that the Ali study is not in the administrative record and of some misquotes from the Baranski study. They contend that the omission of the Ali study means that the trial court could not have evaluated it and that both the misquotes and the omission show bias. As we have seen, the trial court had no need to make its own evaluation of the Ali study, but instead was bound by deferential standard of review. Nor do we see any significance of the omission of a properly-referenced published journal article from the administrative record, or in errors in quotation.

We now turn to appellants' contentions about their request that the trial court take judicial notice of various documents and augment the record with those documents, and their request to take discovery.

We first consider the request for judicial notice and augmentation. Appellants' request included five categories of documents. The court granted the motion as to the documents in Exhibit B, described in the request as "documents proposed to be added to the record of cadmium regulating proceedings."

Appellants also sought to augment the record with nine documents which the OEHHA withheld as privileged in its response to appellants' Public Records Act request. Seven of the documents are email notes from an individual identified as OEHHA's counsel to agency staff and were withheld on the ground of attorney-client privilege. The last two were internal drafts of the MADL statement of reasons, and were withheld on the ground that they were irrelevant and that the request was an attempt to probe the mental processes of decision makers After *in camera* review, the trial court sustained the objection based on attorney-client privilege. As to the remaining documents, the court found that "their only relevance . . . is to show what technical data and literature respondent considered, or did not consider, in adopting a regulation. Such inquiry is improper."

On appeal, appellants contend that the public interest in disclosure of the documents outweighs any need for confidentiality. Legally, they cite *Shepherd v. Superior Court* (1976) 17 Cal.3d 107, *Fairley v. Superior Court* (1998) 66 Cal.App.4th 1414, and *Marylander v. Superior Court* (2000) 81 Cal.App.4th 1119, for their discussion of the limits of the exemptions found in the Public Records Act, and the interaction of those exemptions with Evidence Code section 1040. Appellants do not, however, explain what difference the production of the documents, and their inclusion in the record, would make here. We thus see no ground for reversal. (Cal. Const., art. 6, § 13.)

As to appellants' discovery request, they sought discovery from respondents "as to whether OEHHA considered all of the relevant factors or fully explicated its course of conduct or grounds of decision in adopting the cadmium regulation." Their argument here is that with the discovery, they would have been able to obtain admissible evidence on issues. That bare assertion does not establish error.

Disposition

The judgment is affirmed.

NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

ARMSTRONG, J.

I concur:

TURNER, P.J.

MOSK, J., Concurring

I concur.

The petitioners may well be correct that neither the "person responsible" under Health and Safety Code section 25249.10[1] nor the Office of Environmental Health Hazard Assessment (OEHHA), acting as such a person, can, under that statute, reject "evidence and standards . . . for the listing of such chemical pursuant to subdivision (a) of Section 25249.8" (the listing). (§ 25249.10, subd. (c); see *Association for Retarded Citizens v. Department of Developmental Services* (1985) 38 Cal.3d 384, 391 ["To be valid, such administrative action must be within the scope of authority conferred by the enabling statute"].) Petitioners accept that section 25249.10 does not restrict the selection of which evidence and standards used for the listing of the chemical to rely upon in determining an exemption under section 25249.10.

Petitioners argue, however, that OEHHA is bound by its regulation to accept the most sensitive study used for the listing. But in doing so petitioner relies on only a portion of that regulation. California Code of Regulations, title 22, section 12803, subdivision (a)(4) provides, "The NOEL [No Observable Effect Levels] shall be based on the most sensitive study *deemed to be of sufficient quality*." (Italics added.) Thus, the regulation provides that only the most sensitive study must be used, but the study has to be deemed to be of sufficient quality.

Petitioners contend that if the study is a listed one it has already been "deemed to be of sufficiently quality by virtue of the support for the listing." But a reasonable reading of the regulation is that the study must be "deemed to be of sufficient quality" for purposes of determining the exact amount of the chemical that is toxic and not just for the purpose that the chemical is sufficiently toxic so that it must be listed. As deference should be given to an administrative agency's interpretation of its own regulations

---

[1] Unless otherwise specified, reference to sections shall be those contained in the Health and Safety Code.

(*Olszewski v. Scripps Health* (2003) 30 Cal.4th 798, 821; *Pacific Legal Foundation v. Unemployment Ins. Appeals Bd.* (1981) 29 Cal.3d 101; *Communities for a Better Environment v. State Water Resources Control Bd.* (2003) 109 Cal.App.4th 1089, 1104), we should follow this interpretation.

If petitioners are right that because a study is specified as a document supporting the listing of a chemical, OEHHA has no authority to, in effect, conclude that a study is not of sufficient quality, section 12803, subdivision (a)(4) of the Regulations is invalid, including the portion that the "NOEL shall be based on the most sensitive study." And if that provision is invalid, then OEHHA is not required to rely upon the most sensitive study but may choose among the specified studies supporting the listed chemical. Petitioners seek to utilize a regulation without its qualification. This petitioners cannot do.

I am concerned that the study relied upon by OEHHA—the Ali Study—is not part of the administrative record. We have no way to determine if the decision is arbitrary or capricious. The Supreme Court has stated that "the agency record must provide as complete a basis for judicial review as due diligence makes feasible. It must include any technical matter necessary to enable a lay judge to determine whether the agency's decision has adequate support." (*Franz v. Board of Medical Quality Assurance* (1982) 31 Cal.3d 124, 139; see also *Buckhart v. San Francisco Residential Rent etc., Bd.* (1988) 197 Cal.App.3d 1032, 1036 ["it will be seen that whether the superior court exercises its 'independent judgment' on the record *or* determines whether the Board's findings are supported by the evidence, it is in need of the 'whole administrative record,' *including the hearing's evidence*. Without such a *complete* record the superior court *cannot* comply with Code of Civil Procedure section 1094.5"].)

"Appellants are entitled to have the entire record of the administrative proceedings presented to the court for review. However, appellants have the burden of producing the record when they attack the sufficiency of the evidence." (*Eureka Teachers Assn. v. Board of Education* (1988) 199 Cal.App.3d 353, 367; see *Weinberg v. Cedars-Sinai Medical Center* (2004) 119 Cal.App.4th 1098, 1107 ["'[i]n a [Code of Civil Procedure] section 1094.5 proceeding it is the responsibility of the petitioner to produce a sufficient record of the administrative proceedings; ". . . otherwise the presumption of regularity will prevail . . ."'"].) Even though OEHHA had the burden to establish the requirements for the exemption, petitioners had the burden of proof to establish that OEHHA had acted arbitrarily or capriciously. (See *California Correctional Peace Officers Assn. v. State Personnel Bd.* (1995) 10 Cal.4th 1133, 1153-1154; *Huntington Park Redevelopment Agency v. Duncan* (1983) 142 Cal.App.3d 17, 25.) Here petitioners had the opportunity to add the study to the record. It could have been included among the many documents added at petitioner's request to the record before the trial court. Thus, the absence of the Ali study does not require reversal.

Petitioners are correct that the People adopted Proposition 65 (§ 25249.5, et seq.) to reduce health risks. This court has determined that the People gave some discretion to OEHHA to participate in this process. Because we are dealing with public health, one can only hope that OEHHA's determination is a correct one.

MOSK, J.